ASSOCIATION OF DISPOSABLE DEVICE MANUFACTURERS
Providing industry views on single patient use medical devices

June 24, 1999

BY HAND DELIVERY

Documents Management Branch (HFA-305)
Food and Drug Administration
Room 23
12420 Parklawn Drive
Rockville, Maryland 20857

Re: Comment to Citizen Petition to Ban Reprocessed Single Use Devices: Docket No. 99P-1516.

Dear Sir or Madam:

The Association of Disposable Device Manufacturers (ADDM) respectfully submits the following comments to the referenced Citizen Petition filed by the Medical Device Manufacturers Association (MDMA) which requests that the Commissioner of Food and Drugs issue a proposed regulation identifying reprocessed single use medical devices as banned devices.

ADDM is a trade association of single patient use medical device manufacturers committed to providing information and industry perspectives on issues impacting these devices. We support MDMA's initiatives to protect the public health and bring about the appropriate regulation of reprocessed single use devices.

By their nature, devices labeled for single use only have not been proven safe and effective for multiple use. In fact, evidence exists to conclude that many of these devices, when reprocessed, do not meet the legal standards established for safety and effectiveness because they cannot be adequately cleaned while retaining their functional integrity. Despite this evidence, U.S. patients continue to be exposed to the risks presented by such unsterile or malfunctioning devices because of a lack of decisive action by the Food and Drug Administration (FDA). The FDA must fulfill its role in the protection of these patients by enforcing the legally mandated standard for proving safety and effectiveness – premarket submission.

99P-1516 C1

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Previous Attempts to Bring About Appropriate Regulation

The legal basis for enforcement of the premarket submission regulations on parties who reprocess used single patient use devices was eloquently set forth in a September 5, 1997 citizen petition filed by the Health Industry Manufacturers Association (HIMA). HIMA, MDMA, and several individual manufacturers reinforced these arguments in comments submitted to a December 2, 1997 Advanced Notice of Proposed Rulemaking on a related issue. The agency's response to the HIMA petition, dated July 15, 1998, noted that FDA would not enforce the 510(k) and PMA regulations at that time, taking comfort in a perceived lack of adverse patient outcomes to date. That letter requested data indicative of such events.

Those data have since been provided. On January 27 of this year, ADDM submitted the results of three studies to the Center for Devices and Radiological Health (CDRH), each indicating the high degree of risk associated with the reuse of these used disposable devices. ADDM submitted further data on February 4. In a March 30 reply, CDRH did not directly address the data which it had requested, but instead directed attention to the importance of "input from all stakeholders." The CDRH reply referenced a May 5-6 meeting, sponsored by FDA and the Association for the Advancement of Medical Instrumentation (AAMI) and concluded that CDRH expects to have "formulated [a] proposed strategy" by October 1999 – a date over two years after submission of the HIMA citizen petition.

Data on Health Risks

ADDM's data was reinforced by three separate presentations at the FDA/AAMI meeting which noted changes in critical functionality of various devices. Two of these presentations reported data generated by FDA's own Office of Science and Technology (OST). After noting the material-specific cleaning and functionality obstacles encountered in reprocessing PTCA catheters, FDA's scientists concluded that model by model decision-making as to the appropriateness of reprocessing, such as that inherent in premarket review, was needed. In addition, a Medwatch report discussed at the AAMI meeting indicates that a piece of metal electrode, which broke off a reprocessed electrophysiology catheter during a procedure, remains lodged in the right atrium of a 32 year old patient. This catheter, approved by FDA for single use only, was reprocessed six times by a major third party reprocessor. FDA representatives at the FDA/AAMI meeting alluded to other reports in the MDR database which demonstrate the risks of reprocessing single patient use devices.

The FDA/AAMI meeting held in May illuminated the need for great concern for patient safety stemming from poor cleaning and impaired functionality of reprocessed used single use devices. While FDA's interest in the debate over these devices seems to have increased, many agency comments at the meeting have led ADDM to fear further delay in the resolution of this issue. Specifically, FDA repeatedly commented on 1) the need to reach consensus among the stakeholders, and 2) the international nature of the reuse issue. Neither should shape the agency's course of action. Further time spent attempting to achieve consensus runs counter to the goal of quickly resolving the issue to assure the

safety of U.S. patients. Consensus can not override or delay the law. Similarly, while reuse is certainly an international issue, the FDA has been charged with protecting the health of U.S. citizens. Thus, any hesitation in action attributed to resolving the issue in other countries would be suspect. Compelling data on the risks presented by reused single use devices cannot be ignored any longer.

Enforcement of Current Regulations

In addition to being the legally mandated solution to this problem, enforcement of the premarket submission regulations also serves to address the very real patient safety concerns of many stakeholders. Numerous participants at the FDA/AAMI meeting expressed their concern with the safety of current reuse practices, and all agreed the patient safety should be the agency's paramount concern. Enforcement of premarket submission requirements for reprocessed disposable devices would provide all patients with an assurance of the safety and effectiveness for any device used during their procedures – new or reprocessed. In addition, numerous stakeholders noted that enforcement of the premarket submission requirements would address their concerns. These included representatives of state government, operating room nurses, hospital central sterilization personnel, ethicists, infection control professionals, device design experts and other health care workers. Enforcement of the premarket submission requirements would also address the need for model-by-model data raised by CDRH's own internal study on PTCA catheters presented by OST.

FDA has noted that the current degree of regulatory enforcement on reprocessors of used disposable devices is inadequate and that reprocessors are "manufacturers" under the law. The agency has also, however, indicated that it may not enforce the premarket submission requirements because of resource concerns. This analysis and excuse was most notable in the remarks of the Office of Device Evaluation (ODE) at the FDA/AAMI meeting. ODE commented that, while the information available leads to the conclusion that this is a "device by device, facility by facility issue," implementation of the premarket regulations would be unmanageable from an FDA perspective presumably because of the potential for numerous submissions from hospitals and reprocessors. The threat of an onslaught of premarket submissions leading to resource allocation issues within ODE is unfounded. Hospital representatives at the FDA/AAMI meeting explicitly stated that hospitals would not submit 510(k)s and PMAs for reprocessed single use devices. This leaves only third party commercial reprocessors to submit premarket applications. However, ODE itself has noted that validation data currently generated by reprocessors "is marginal at best and would be not support premarket clearance or approval." Without the data necessary to support such clearance or approval, third party reprocessors could not flood FDA with 510(k)s and PMAs.

In light of its realization that current data are below the standard set for safety and effectiveness, it is particularly alarming that FDA has not taken immediate action to require

premarket submission. Considering the legal requirements, the significant concerns for patient safety and the issues raised by the stakeholders, FDA must marshal its resources to assure the safety and effectiveness of reprocessed single use devices according to the legally mandated standard – premarket submission.

Conclusion

Under the current enforcement paradigm set up by FDA, there is no method for determining whether a reprocessed single use device is safe and effective before it is used on a patient. The reprocessor itself, whose financial success is dependent upon the widest possible use of reprocessing, is the only judge of the appropriateness of its practices. FDA cannot continue to stand by, formulating policy and striving to reach consensus, while U.S. patients are exposed to the risks of reused disposable devices.

This issue has been discussed for well over two years. Any further delay brought about by a call for data in a form other than a premarket submission, the organization of additional stakeholder meetings, or discussions of international policy can not be justified in light of the current statutory framework under which the agency must operate. The path to patient safety, and compliance with the law, is clear. CDRH must not delay in announcing a decisive policy to require premarket submission for any reprocessed single patient use device.

In closing, ADDM appreciates the opportunity to comment on the MDMA Citizen Petition. Should you have any questions regarding these comments, please call me at 202-737-7554.

Respectfully submitted,

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President

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